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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/447,228	11/22/1999	GENE PHILLIP DIPOTO	0231/0314-00	3547
<div>7590 06/29/2010</div> <div>JOEL R PETROW ESQ CHIEF PATENT COUNSEL SMITH & NEPHEW NORTH AMERICA 1450 BROOKS ROAD MEMPHIS, TN 38116</div> <div>EXAMINER NGUYEN, VI X</div> <div>ART UNIT 3731 PAPER NUMBER</div> <div>MAIL DATE 06/29/2010 DELIVERY MODE PAPER</div>				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/447,228

Applicant(s)

DIPOTO ET AL.

Examiner

VICTOR X. NGUYEN

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 52-70 and 88-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 52-70 and 88-93 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SEA-3)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

1. The indicated allowability of claims 1-19, 21-71, 73-99 and 102-110 (mailed out on 1/3/2006) are withdrawn in view of the newly discovered reference(s) to Hayhurst; Cerier; Somers; Philips. Rejections based on the newly cited reference(s) follow. Further, A Supervisory Patent Examiner has approved of reopening prosecution by signing below.
2. Claims 1-18, 52-70, 88-93 are pending in this present application.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: “engaging member” as recited in claim 52; “suture mount” as recited in claims 1, 13; and “non-helical circumferential ridge” as recited in claim 62.
4. The amended claims filed on 2/23/09 which are listed in appendix D are not in compliant with reissue amendment format. All amendments should be made with markings to show changes with respect to the original patent, not the previous amendment and that applicant should submit a full listing of all claims as currently pending, in compliant amendment format.. Note that, the intervening amendment filed on 2/23/09 is also not in compliant for the same reason noted above. The applicant needs to resubmit a full listing of all pending claims including current status identifiers, as well as markings to show changes made with respect to the original patent. Because there are so many different amendment papers and appendices in the file, this single full claim listing will serve to clarify, on the record, the correct and current version of claims pending in the file. See MPEP 1453 (V), (A-D) and See MPEP 1453 (V), (D).

Consent of Assignee

5. In a consent of assignee filed on 4/24/00, while assignee has consented to file the reissue application, there is no indication that the assignee has “an undivided interest in said original patent”.

Declaration

6. The declaration filed on 4/24/00 is defective. Accordingly, “The original filed claims were (and the claims of the 5,690,676 patent are) directed to an anchor and driver assembly; whereas the specification more broadly describes, for example, an anchor having a rigid body defining a generally transverse opening extending through the body for receiving suture,”. However, it is stated in MPEP 1414 (II)(C) states “Any error in the claims must be identified by reference to the specific claim(s) and the specific claim language wherein lies the error.” (emphasis added). Applicant failed to positive identify by reference to a particular claim (i.e. specific claim language) which contain the alleged error. It is worth-noting that patent ‘676 is not only drawn to an anchor and driver assembly. See for instance, claim 1 which is drawn to an anchor.

Therefore, Claims 1-18, 52-70, 88-93 are rejected under 35 USC 251 for having an improper oath/declaration.

Supplemental declaration

7. Amendments to claims subsequent to filing applicant’s declaration have substantive changes relative to the originally filed claims in the reissue application. Therefore, applicant is required to file a supplemental declaration containing catch-all error statement. See MPEP 1414.01 & MPEP 1444 (II) for details. Further, applicant is reminded that this must be signed by the inventor(s) NOT the assignee since this is a broadening application.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Somers et al US 4,632,100.

Claim 1: Somers et al disclose an anchor 10 for securing a suture to bone, comprising: an elongated body 11 having a proximal region terminating in a proximal end, and a distal region terminating in a distal end configured for insertion into a hole in the bone; said proximal region including an element (figures 1-2, 4, 5a) configured for positive axial inter-engagement with a corresponding element of a driver 12 for insertion of said anchor into the hole, said element of said proximal region including one of a protrusion 15 or a recess which axially interlocks with a corresponding recess or protrusion, respectively, of the corresponding driver element; at least one ridge 14, disposed on an exterior surface of said body, for engaging the bone after insertion to resist withdrawal of said anchor; and a suture 24 mount carried by said elongated body.

Claims 2-3: Somers et al disclose the recess 15 includes an opening in said proximal region of said anchor or in said driver; where the element of said anchor 10 includes a projection

extending from said elongated body for engaging a matching socket of the corresponding driver element 12.

Claim 13: Sommers et al disclose an anchor member 10 including an elongated body 11 having a proximal region terminating in a proximal end, and a distal region terminating in a distal end configured for insertion into a hole in a bone; a driver member 12 having a handle member and a shaft member, said shaft member having a drive element 12 at its distal end; said proximal region of said anchor member including an element (as best seen in figures 1-2, 4, 5a) configured for positive axial inter-engagement with said drive element for insertion of said anchor into the hole by said driver member, said element of said anchor member including one of a protrusion 15 or a recess which axially interlocks with a corresponding recess or protrusion, respectively, of said drive element 12; at least one ridge 14, disposed on an exterior surface of said body, for engaging the bone after insertion to resist withdrawal of said anchor member; and a suture 24 mount carried by said elongated body.

Claims 14-15: Sommers et al disclose the driver member 12 has a passageway there-through, and said anchor member 10 has an opening therein communicable with said passageway and with said suture 24 mount; and wherein further comprising a suture member 24 attached to said anchor member by said suture mount, passing through said opening, and being positioned in said passageway as best seen in figures 2, 4.

9. Claims 1-18, 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayhurst US 4,741,330.

Claim 1: Hayhurst discloses an anchor 10 for securing a suture 12 to bone, comprising: an elongated body 14 having a proximal region terminating in a proximal end, and a distal region terminating in a distal end configured for insertion into a hole in the bone; said proximal region including an element 16 configured for positive axial inter-engagement with a corresponding element of a driver (in combination of hollow tube 14, inner tube 16, see col. 5, lines 4-68, figures 1-6) for insertion of said anchor into the hole, said element of said proximal region including one of a protrusion 33 or a recess which axially interlocks with a corresponding recess or protrusion, respectively, of the corresponding driver element; at least one ridge 28, disposed on an exterior surface of said body, for engaging the bone after insertion to resist withdrawal of said anchor; and a suture 12 mount carried by said elongated body.

Claims 2-4: Hayhurst discloses the recess 33 includes an opening in said proximal region of said anchor or in said driver; where the element of said anchor 10 includes a projection extending from said elongated body for engaging a matching socket of the corresponding driver element (in combination of hollow tube 14, inner tube 16, see col. 5, lines 4-68, figures 1-6), and wherein the anchor is narrower in a first dimension (as best seen in fig. 6) along another dimension (in a larger dimension in fig. 2). As to claims 5-12, Hayhurst discloses the invention substantially as claimed as best seen in figures 1-6.

Claim 13: Hayhurst discloses an anchor member 10 including an elongated body 14 having a proximal region terminating in a proximal end, and a distal region terminating in a distal end configured for insertion into a hole in a bone; a driver member (in combination of hollow tube 14, inner tube 16, see col. 5, lines 4-68, figures 1-6) having a handle member and a shaft member, said shaft member having a drive element at its distal end; said proximal region

of said anchor member including an element 16 configured for positive axial inter-engagement with said drive element for insertion of said anchor into the hole by said driver member, said element of said anchor member including one of a protrusion 33 or a recess which axially interlocks with a corresponding recess or protrusion, respectively, of said drive element; at least one ridge 28, disposed on an exterior surface of said body, for engaging the bone after insertion to resist withdrawal of said anchor member; and a suture 12 mount carried by said elongated body.

Claims 14-16: Hayhurst discloses the driver member has a passageway (fig. 2) there-through, and said anchor member 10 has an opening therein communicable with said passageway and with said suture 12 mount; wherein further comprising a suture member 12 attached to said anchor member by said suture mount, passing through said opening, and being positioned in said passageway; and wherein the anchor member and the drive member are capable of receiving a guidewire through the passageway as best seen in figures 2 and 4.

Claims 17-18: Hayhurst discloses said driver element includes a pin 34 arranged transversely to a longitudinal axis of said shaft member (fig. 2), and said element of said anchor member includes a socket in said elongated body for receiving said pin 34; wherein said socket includes a slot having an open (where the inner tube 16 goes through) proximal end and a closed distal end, said closed distal end being substantially the same size as said pin 34 and said slot being narrower than said pin, thereby to provide the positive axial inter-engagement with said pin as best seen in figures 2-3.

Claim 88: Hayhurst discloses an anchor assembly comprising an anchoring means (10), the anchoring means is attached to the suture (12) and a drive means, wherein the drive means includes a hollow needle (14) having a collar (28), an inner tube (16) having a key (34) and an annular flange (32) (col. 5 lines 4-68; figures 1-6). It is acknowledged that, Hayhurst does disclose a drive tool including a mount for releasably receiving a second portion of the suture to enable said anchor body to be secured to said drive tool at least in part attaching the second portion of the suture to the mount. Further, this limitation is merely an intended function or use of the so-called "mount". It is reasonably expected that one of the collar (28), key (34) or annular flange is taken to be embraced by the term "mount" (i.e. broadly read to be an elevation or an element for mounting/securing). Anyone of these components is clearly **capable of performing the intended use or function of securing an anchor body** by simply forming a suture knot around of one of them.

10. Claims 52-70, 89-92 are rejected under 35 U.S.C. 102(e) as being anticipated by Hayhurst US 5,037,422.

Claim 52: Hayhurst discloses a rigid body defining a generally transverse opening 24 extending through said body for receiving the suture 22, said opening having open ends, said body having an outer surface defining a pair of suture 22 receiving channels, each suture 22 receiving channel being aligned with one of said open ends, said body including an engaging member configured to engage the bone upon insertion to resist withdrawal of said anchor from the bone as best seen in figures 1-2 and 6.

Claims 53-54: Hayhurst discloses the suture 22 receiving channels extend through said engaging member; and wherein said suture 22 receiving channels extend to a proximal end of said body.

Claims 55-56: Hayhurst discloses the engaging member comprises a circumferential ridge 14; and wherein the circumferential ridge is non-helically arranged. It is noted that the anchor comprises barbs or ridges 14 which is taken to be embraced by the limitation of a non-helically extending exterior enlargement to engage against a surface of the bone hole to resist the anchor withdrawal and a receiving opening 24 where a suture is threaded through (see abstract).

Claims 57-59: Hayhurst discloses the circumferential ridge 14 includes a distal, chamfered surface; wherein said circumferential ridge 14 includes a proximal surface orientated transversely to a longitudinal axis of the body (figures 1, 6); and wherein the proximal surface is perpendicular to the longitudinal axis of the body (fig. 7). As to claims 60-70, Hayhurst's 422 discloses the invention substantially as claimed as best seen in figures 1-2 and 6.

Claims 89-92: As shown in figures 1-2 and 6, a bone anchor is inserted into a hole of a bone (38). The anchor comprises barbs (14; taken to be embraced by the limitation a non-helically extending exterior enlargement) to engage against a surface of the bone hole to resist anchor withdrawal, and a receiving opening (24) where a suture is threaded through. (abstract). It is noted that Hayhurst does characterize his anchor to be rigid, an alternative embodiment shown in figure 6 is expected to be relatively rigid to a certain extent. Hayhurst discloses using bioabsorbable (e.g. polyglycolic acid, polylactic acid), polypropylene, polyester, etc. (col. 5 lines 1-5). The resultant anchor of Hayhurst using the above polymers should reasonably expect to be

rigid to a certain extent. In fact, the parent patent 5,690,676 teaches using the same bioabsorbable polymers as those taught by Hayhurst. Therefore, these claims are anticipated by Hayhurst.

11. Claim 93 is rejected under 35 U.S.C. 102(e) as being anticipated by Phillips US 5,203,864.

Claim 93: Phillips discloses attaching a first portion of a suture (see col. 1, lines 38-44, lines 63-66) to said anchor body 18', attaching a second portion of the suture to said drive tool 11 such that said anchor body is secured to said drive tool at least in part by attaching the second portion of the suture to the drive tool as best seen in figures 8-10.

12. Claims 1-18, 52-70, 88-93 are rejected under 35 U.S.C. 102(e) as being anticipated by Cerier et al US 5,100,417

Claim 1: Cerier discloses an anchor 16 for securing a suture 18 to bone, comprising: an elongated body 12 having a proximal region terminating in a proximal end, and a distal region terminating in a distal end configured for insertion into a hole in the bone; said proximal region including an element as best seen in figures 2-3 configured for positive axial inter-engagement with a corresponding element of a driver (10) for insertion of said anchor into the hole, said element of said proximal region including one of a protrusion or a recess (figures 2-3, 8) which axially interlocks with a corresponding recess or protrusion, respectively, of the corresponding driver element; at least one ridge 62, disposed on an exterior surface of said body, for engaging the bone after insertion to resist withdrawal of said anchor; and a suture 18 mount carried by said elongated body. As to claims 2-18, 52-70 and 88-93 are anticipated by Cerier as best seen in figures 1-9.

Response to Arguments

13. Applicant's arguments filed on 2/23/2009 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTOR X. NGUYEN whose telephone number is (571)272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor X Nguyen/
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
6/26/2010